Mr. Brian Ramey Eli Lilly and Company 1650 Lilly Road Lafayette, IN 47909

Re: Significant Source Modification No: 157-12478-00006

Dear Mr. Ramey:

Eli Lilly and Company applied for a Part 70 operating permit on October 10, 1996 to a pharmaceutical processing plant. An application to modify the source was received on July 7, 2000. Pursuant to 326 IAC 2-7-10.5 the following emission units are approved for construction at the source:

- (a) One (1) 1,000 gallon general process tank, designated as TK 40-11, located in an existing building designated as T27, and capable of being controlled by the existing Regenerative Thermal Oxidizer (RTO) or condenser for VOC emissions. CO, NOX, and SO2 emissions will be controlled voluntarily by existing RTOs and scrubbers as appropriate).
- (b) One (1) 500 gallon charging tank, designated as TK 53-10, located in an existing building designated as T27, and capable of being controlled by the existing Regenertive Thermal Oxidizer (RTO) or condenser for VOC emissions.

The proposed Significant Source Modification approval will be incorporated into the pending Part 70 permit application pursuant to 326 IAC 2-7-10.5(I)(3). If there are no changes to the proposed construction of the emission units, the source may begin operating on the date that IDEM receives an affidavit of construction pursuant to 326 IAC 2-7-10.5(h). If there are any changes to the proposed construction the source can not operate until an Operation Permit Validation Letter is issued.

This decision is subject to the Indiana Administrative Orders and Procedures Act - IC 4-21.5-3-5. Pursuant to Contract No. A305-0-00-36, IDEM, OAM has assigned the processing of this application to Eastern Research Group, Inc., (ERG). Therefore, questions should be directed to Mike Pring, ERG, P.O. Box 2010, Morrisville, North Carolina 27560, or call (919) 468-7840 to speak directly to Mr. Pring. Questions may also be directed to Duane Van Laningham at IDEM, OAM, 100 North Senate Avenue, P.O. Box 6015, Indianapolis, Indiana, 46206-6015, or call (800) 451-6027, press 0 and ask for Duane Van Laningham, or extension 3-6878, or dial (317) 233-6878.

Sincerely,

Paul Dubenetzky, Chief Permits Branch Office of Air Management

Attachments ERG/MP

cc: File -Tippecanoe County
U.S. EPA, Region V
Tippecanoe County Health Department
Air Compliance Section Inspector Eric Courtright
Compliance Data Section - Karen Nowak
Administrative and Development - Janet Mobley
Technical Support and Modeling - Michele Boner

PART 70 SIGNIFICANT SOURCE MODIFICATION OFFICE OF AIR MANAGEMENT

Eli Lilly and Company 1650 Lilly Road Lafayette, Indiana 47909

(herein known as the Permittee) is hereby authorized to operate subject to the conditions contained herein, the emission units described in Section A (Source Summary) of this permit.

This approval is issued in accordance with 326 IAC 2 and 40 CFR Part 70 Appendix A and contains the conditions and provisions specified in 326 IAC 2-7 as required by 42 U.S.C. 7401, et. seq. (Clean Air Act as amended by the 1990 Clean Air Act Amendments), 40 CFR Part 70.6, IC 13-15 and IC 13-17.

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Issued by: Paul Dubenetzky, Branch Chief Office of Air Management	Issuance Date:

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SECTION A

SOURCE SUMMARY

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This permit is based on information requested by the Indiana Department of Environmental Management (IDEM), Office of Air Management (OAM). The information describing the source contained in conditions A.1 through A.3 is descriptive information and does not constitute enforceable conditions. However, the Permittee should be aware that a physical change or a change in the method of operation that may render this descriptive information obsolete or inaccurate may trigger requirements for the Permittee to obtain additional permits or seek modification of this permit pursuant to 326 IAC 2, or change other applicable requirements presented in the permit application.

General Information [326 IAC 2-7-4(c)] [326 IAC 2-7-5(15)]

The Permittee owns and operates a stationary source that produces pharmaceutical products.

Responsible Official: Kenny McCleary

Source Address: 1650 Lilly Road, Lafayette, Indiana 47909 Mailing Address: 1650 Lilly Road, Lafayette, Indiana 47909

Phone Number: 765-477-4006 SIC Code: 2834 and 2879 **County Location: Tippecanoe**

County Status: Attainment for all criteria pollutants

Source Status: Part 70 Permit Program,

> Major Source, under PSD or Emission Offset Rules; Major Source, Section 112 of the Clean Air Act

Emissions units and Pollution Control Equipment Summary

This stationary source is approved to construct and operate the following emissions units and pollution control devices:

- (a) One (1) 1,000 gallon general process tank, designated as TK 40-11, located in an existing building designated as T27, and capable of being controlled by the existing Regenerative Thermal Oxidizer (RTO) or condenser for VOC emissions. CO, emissions will be controlled voluntarily by existing RTOs. NOx and SO2 emissions will be controlled voluntarily by scrubbers.
- (b) One (1) 500 gallon charging tank, designated as TK 53-10, located in an existing building designated as T27, and capable of being controlled by the existing Regenerative Thermal Oxidizer (RTO) or condenser for VOC emissions.

The point source emissions from the process vessels may vent directly to RTO1 or RTO2, or they may first vent to scrubbers, process control condensers, vacuum sources, or through other process vessels before going to the RTO. If venting the process vessels to the RTO would cause a safety concern, the process vessels may vent to an alternative pollution control device that complies with 326 IAC 8-5-3.

Part 70 Permit Applicability [326 IAC 2-7-2] A.3

This stationary source has submitted a Part 70 permit application TV 157-6879-00006 on October 6, 1996, pursuant to 326 IAC 2-7-2 (Applicability) because:

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(a) It is a major source, as defined in 326 IAC 2-7-1(22);

(b) It is a source in a source category designated by the United States Environmental Protection Agency (U.S. EPA) under 40 CFR 70.3 (Part 70 - Applicability).

SECTION B GENERAL CONSTRUCTION CONDITIONS

B.1 Permit No Defense [IC 13]

This permit to construct does not relieve the Permittee of the responsibility to comply with the provisions of the Indiana Environmental Management Law (IC 13-11 through 13-20; 13-22 through 13-25; and 13-30), the Air Pollution Control Law (IC 13-17) and the rules promulgated thereunder, as well as other applicable local, state, and federal requirements.

B.2 Definitions [326 IAC 2-7-1]

Terms in this permit shall have the definition assigned to such terms in the referenced regulation. In the absence of definitions in the referenced regulation, any applicable definitions found in IC 13-11, 326 IAC 1-2, and 326 IAC 2-1.1-1 shall prevail.

B.3 Effective Date of the Permit [IC13-15-5-3]

Pursuant to IC 13-15-5-3, this permit becomes effective upon its issuance.

B.4 Significant Source Modification [326 IAC 2-7-10.5(h)]

This document shall also become the approval to operate pursuant to 326 IAC 2-7-10.5(h) when, prior to start of operation, the following requirements are met:

- (a) The attached affidavit of construction shall be submitted to the Office of Air Management (OAM), Permit Administration & Development Section, verifying that the emission units were constructed as proposed in the application. The emissions units covered in the Significant Source Modification approval may begin operating on the date the affidavit of construction is postmarked or hand delivered to IDEM if constructed as proposed.
- (b) If actual construction of the emissions units differs from the construction proposed in the application, the source may not begin operation until the source modification has been revised pursuant to 326 IAC 2-7-11 or 326 IAC 2-7-12 and an Operation Permit Validation Letter is issued.
- (c) If construction is completed in phases; i.e., the entire construction is not done continuously, a separate affidavit must be submitted for each phase of construction. Any permit conditions associated with operation start up dates such as stack testing for New Source Performance Standards (NSPS) shall be applicable to each individual phase.
- (d) The Permittee shall receive an Operation Permit Validation Letter from the Chief of the Permit Administration & Development Section and attach it to this document.

This Significant Source Modification approval shall be incorporated into the Permitee's Part 70 Operating Permit.

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SECTION C

SOURCE OPERATION CONDITIONS

C.1 Certification [326 IAC 2-7-4(f)][326 IAC 2-7-6(1)][326 IAC 2-7-5(3)(C)]

- Where specifically designated by this approval or required by an applicable requirement, any application form, report, or compliance certification submitted under this approval shall contain certification by a responsible official of truth, accuracy, and completeness. This certification, shall state that, based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate, and complete.
- (b) One (1) certification shall be included, on the attached Certification Form, with each submittal where certification is required by the terms of the applicable rule or specifically designated by this approval.
- (c) A responsible official is defined at 326 IAC 2-7-1(34).
- C.2 Preventive Maintenance Plan [326 IAC 2-7-5(1),(3) and (13)] [326 IAC 2-7-6(1) and (6)] [326 IAC 1-6-3]
 - If required by specific condition(s) in Section D of this approval, the Permittee shall prepare (a) and maintain Preventive Maintenance Plans (PMP) upon startup after issuance of this approval, including the following information on each facility:
 - (1) Identification of the individual(s) responsible for inspecting, maintaining, and repairing emission control devices;
 - (2) A description of the items or conditions that will be inspected and the inspection schedule for said items or conditions:
 - Identification and quantification of the replacement parts that will be maintained in (3)inventory for quick replacement.

If due to circumstances beyond its control, the PMP cannot be prepared and maintained within the above time frame, the Permittee may extend the date an additional ninety (90) days provided the Permittee notifies:

Indiana Department of Environmental Management Compliance Branch, Office of Air Management 100 North Senate Avenue, P. O. Box 6015 Indianapolis, Indiana 46206-6015

- (b) The Permittee shall implement the Preventive Maintenance Plans as necessary to ensure that failure to implement the Preventive Maintenance Plan does not cause or contribute to a violation of any limitation on emissions or potential to emit.
- (c) PMP's shall be submitted to IDEM, OAM, upon request and shall be subject to review and approval by IDEM, OAM. IDEM, OAM, may require the Permittee to revise its Preventive Maintenance Plan whenever lack of proper maintenance causes or contributes to any violation.

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C.3 Permit Amendment or Modification [326 IAC 2-7-11] [326 IAC 2-7-12]

- (a) The Permittee must comply with the requirements of 326 IAC 2-7-11 or 326 IAC 2-7-12 whenever the Permittee seeks to amend or modify this approval.
- (b) Any application requesting an amendment or modification of this approval shall be submitted to:

Indiana Department of Environmental Management Permits Branch, Office of Air Management 100 North Senate Avenue, P.O. Box 6015 Indianapolis, Indiana 46206-6015

Any such application should be certified by the "responsible official" as defined by 326 IAC 2-7-1(34) only if a certification is required by the terms of the applicable rule

(c) The Permittee may implement administrative amendment changes addressed in the request for an administrative amendment immediately upon submittal of the request. [326 IAC 2-7-11(c)(3)]

C.4 Opacity [326 IAC 5-1]

Pursuant to 326 IAC 5-1-2 (Opacity Limitations), except as provided in 326 IAC 5-1-3 (Temporary Exemptions), opacity shall meet the following, unless otherwise stated in this approval:

- (a) Opacity shall not exceed an average of forty percent (40%) in any one (1) six (6) minute averaging period as determined in 326 IAC 5-1-4.
- (b) Opacity shall not exceed sixty percent (60%) for more than a cumulative total of fifteen (15) minutes (sixty (60) readings as measured according to 40 CFR 60, Appendix A, Method 9 or fifteen (15) one (1) minute nonoverlapping integrated averages for a continuous opacity monitor) in a six (6) hour period.

C.5 Operation of Equipment [326 IAC 2-7-6(6)]

Except as otherwise provided in this approval, all air pollution control equipment listed in this approval and used to comply with an applicable requirement shall be operated at all times that the emission units vented to the control equipment are in operation.

Testing Requirements [326 IAC 2-7-6(1)]

C.6 Performance Testing [326 IAC 3-6][326 IAC 2-1.1-11]

(a) Compliance testing on new emission units shall be conducted within 60 days after achieving maximum production rate, but no later than 180 days after initial start-up, if specified in Section D of this approval. All testing shall be performed according to the provisions of 326 IAC 3-6 (Source Sampling Procedures), except as provided elsewhere in this approval, utilizing any applicable procedures and analysis methods specified in 40 CFR 51, 40 CFR 60, 40 CFR 61, 40 CFR 63, 40 CFR 75, or other procedures approved by IDEM, OAM.

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A test protocol, except as provided elsewhere in this approval, shall be submitted to:

Indiana Department of Environmental Management Compliance Data Section, Office of Air Management 100 North Senate Avenue, P. O. Box 6015 Indianapolis, Indiana 46206-6015

no later than thirty-five (35) days prior to the intended test date. The Permittee shall submit a notice of the actual test date to the above address so that it is received at least two weeks prior to the test date.

(b) All test reports must be received by IDEM, OAM within forty-five (45) days after the completion of the testing. An extension may be granted by the IDEM, OAM, if the source submits to IDEM, OAM, a reasonable written explanation within five (5) days prior to the end of the initial forty-five (45) day period.

The documentation submitted by the Permittee does not require certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

Compliance Monitoring Requirements [326 IAC 2-7-5(1)] [326 IAC 2-7-6(1)]

C.7 Compliance Monitoring [326 IAC 2-7-5(3)] [326 IAC 2-7-6(1)]

Compliance with applicable requirements shall be documented as required by this approval. All monitoring and record keeping requirements not already legally required shall be implemented upon startup. The Permittee shall be responsible for installing any necessary equipment and initiating any required monitoring related to that equipment. If due to circumstances beyond its control, that equipment cannot be installed and operated within ninety (90) days, the Permittee may extend the compliance schedule related to the equipment for an additional ninety (90) days provided the Permittee notifies:

Indiana Department of Environmental Management Compliance Branch, Office of Air Management 100 North Senate Avenue, P. O. Box 6015 Indianapolis, Indiana 46206-6015

in writing, prior to the end of the initial ninety (90) day compliance schedule, with full justification of the reasons for the inability to meet this date.

The notification which shall be submitted by the Permittee does require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

Corrective Actions and Response Steps [326 IAC 2-7-5] [326 IAC 2-7-6]

- C.8 Compliance Monitoring Plan Failure to Take Response Steps [326 IAC 2-7-5][326 IAC 2-7-6] [326 IAC 1-6]
 - (a) The Permittee is required to implement a compliance monitoring plan to ensure that reasonable information is available to evaluate its continuous compliance with applicable requirements. This compliance monitoring plan is comprised of:

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- (1) This condition;
- (2) The Compliance Determination Requirements in Section D of this approval;
- (3) The Compliance Monitoring Requirements in Section D of this approval;
- (4) The Record Keeping and Reporting Requirements in Section C (Monitoring Data Availability, General Record Keeping Requirements, and General Reporting Requirements) and in Section D of this approval; and
- (5) A Compliance Response Plan (CRP) for each compliance monitoring condition of this approval. CRP's shall be submitted to IDEM, OAM upon request and shall be subject to review and approval by IDEM, OAM. The CRP shall be prepared within ninety (90) days after issuance of this approval by the Permittee and maintained on site, and is comprised of:
 - (A) Response steps that will be implemented in the event that compliance related information indicates that a response step is needed pursuant to the requirements of Section D of this approval; and
 - (B) A time schedule for taking such response steps including a schedule for devising additional response steps for situations that may not have been predicted.
- (b) For each compliance monitoring condition of this approval, appropriate response steps shall be taken when indicated by the provisions of that compliance monitoring condition. Failure to perform the actions detailed in the compliance monitoring conditions or failure to take the response steps within the time prescribed in the Compliance Response Plan, shall constitute a violation of the approval unless taking the response steps set forth in the Compliance Response Plan would be unreasonable.
- (c) After investigating the reason for the excursion, the Permittee is excused from taking further response steps for any of the following reasons:
 - (1) The monitoring equipment malfunctioned, giving a false reading. This shall be an excuse from taking further response steps providing that prompt action was taken to correct the monitoring equipment.
 - (2) The Permittee has determined that the compliance monitoring parameters established in the approval conditions are technically inappropriate, has previously submitted a request for an administrative amendment to the approval, and such request has not been denied or;
 - An automatic measurement was taken when the process was not operating; or
 - (4) The process has already returned to operating within "normal" parameters and no response steps are required.

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(d) Records shall be kept of all instances in which the compliance related information was not met and of all response steps taken. In the event of an emergency, the provisions of 326 IAC 2-7-16 (Emergency Provisions) requiring prompt corrective action to mitigate emissions shall prevail.

C.9 Actions Related to Noncompliance Demonstrated by a Stack Test [326 IAC 2-7-5] [326 IAC 2-7-6]

- (a) When the results of a stack test performed in conformance with Section C Performance Testing, of this approval exceed the level specified in any condition of this approval, the Permittee shall take appropriate corrective actions. The Permittee shall submit a description of these corrective actions to IDEM, OAM, within thirty (30) days of receipt of the test results. The Permittee shall take appropriate action to minimize emissions from the affected facility while the corrective actions are being implemented. IDEM, OAM shall notify the Permittee within thirty (30) days, if the corrective actions taken are deficient. The Permittee shall submit a description of additional corrective actions taken to IDEM, OAM within thirty (30) days of receipt of the notice of deficiency. IDEM, OAM reserves the authority to use enforcement activities to resolve noncompliant stack tests.
- (b) A retest to demonstrate compliance shall be performed within one hundred twenty (120) days of receipt of the original test results. Should the Permittee demonstrate to IDEM, OAM that retesting in one-hundred and twenty (120) days is not practicable, IDEM, OAM may extend the retesting deadline. Failure of the second test to demonstrate compliance with the appropriate approval conditions may be grounds for immediate revocation of the approval to operate the affected facility.

The documents submitted pursuant to this condition do not require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

Record Keeping and Reporting Requirements [326 IAC 2-7-5(3)] [326 IAC 2-7-19]

C.10 Monitoring Data Availability [326 IAC 2-7-6(1)] [326 IAC 2-7-5(3)]

- (a) With the exception of performance tests conducted in accordance with Section C-Performance Testing, all observations, sampling, maintenance procedures, and record keeping, required as a condition of this approval shall be performed at all times the equipment listed in Section D.1 is operating at normal representative conditions and is emitting a pollutant for which the approval requires emission controls.
- (b) As an alternative to the observations, sampling, maintenance procedures, and record keeping of subsection (a) above, when the equipment listed in Section D of this approval is not operating, the Permittee shall either record the fact that the equipment is shut down or perform the observations, sampling, maintenance procedures, and record keeping that would otherwise be required by this approval.
- (c) If the equipment listed in Section D is operating but abnormal conditions prevail, which may increase emissions of a pollutant for which the approval requires emission control, additional observations and sampling should be taken with a record made of the nature of the abnormality.

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(d) If for reasons beyond its control, the operator fails to make required observations, sampling, maintenance procedures, or record keeping, reasons for this must be recorded.

- (e) At its discretion, IDEM may excuse such failure providing adequate justification is documented and such failures do not exceed five percent (5%) of the operating time in any quarter.
- (f) Temporary, unscheduled unavailability of staff qualified to perform the required observations, sampling, maintenance procedures, or record keeping shall be considered a valid reason for failure to perform the requirements stated in (a) above.

C.11 General Record Keeping Requirements [326 IAC 2-7-5(3)][326 IAC 2-7-6]

- (a) Records of all required monitoring data and support information shall be retained for a period of at least five (5) years from the date of monitoring sample, measurement, report, or application. These records shall be kept at the source location for a minimum of three (3) years and available upon the request of an IDEM, OAM, representative. The records may be stored elsewhere for the remaining two (2) years as long as they are available upon request. If the Commissioner makes a written request for records to the Permittee, the Permittee shall furnish the records to the Commissioner within a reasonable time.
- (b) Records of required monitoring information shall include, where applicable:
 - (1) The date, place, and time of sampling or measurements;
 - (2) The dates analyses were performed;
 - (3) The company or entity performing the analyses;
 - (4) The analytic techniques or methods used;
 - (5) The results of such analyses; and
 - (6) The operating conditions existing at the time of sampling or measurement.
- (c) Support information shall include, where applicable:
 - (1) Copies of all reports required by this approval;
 - (2) All original strip chart recordings for continuous monitoring instrumentation;
 - (3) All calibration and maintenance records;

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(4) Records of preventive maintenance shall be sufficient to demonstrate that failure to implement the Preventive Maintenance Plan did not cause or contribute to a violation of any limitation on emissions or potential to emit. To be relied upon subsequent to any such violation, these records may include, but are not limited to: work orders, parts inventories, and operator's standard operating procedures. Records of response steps taken shall indicate whether the response steps were performed in accordance with the Compliance Response Plan required by Section C - Compliance Monitoring Plan - Failure to take Response Steps, of this approval, and whether a deviation from an approval condition was reported. All records shall briefly describe what maintenance and response steps were taken and indicate who performed the tasks.

(d) All record keeping requirements not already legally required shall be implemented upon startup.

SECTION D.1

FACILITY OPERATION CONDITIONS

Facility Description [326 IAC 2-7-5(15)]:

- (a) One (1) 1,000 gallon general process tank, designated as TK 40-11, located in an existing building designated as T27, and capable of being controlled by the existing Regenerative Thermal Oxidizer (RTO) or condenser for VOC emissions. CO emissions will be controlled voluntarily by existing RTOs. NOx and SO2 emissions will be controlled voluntarily by scrubbers.
- (b) One (1) 500 gallon charging tank, designated as TK 53-10, located in an existing building designated as T27, and capable of being controlled by the existing Regenerative Thermal Oxidizer (RTO) or condenser for VOC emissions.

(The information describing the process contained in this facility description box is descriptive only and does not constitute enforceable conditions.)

Emission Limitations and Standards

D.1.1 Miscellaneous Operation: Synthesized Pharmaceutical Manufacturing [326 IAC 8-5-3]

- (a) Pursuant to 326 IAC 8-5-3 when using condensers to control the VOC emissions from these process tanks the outlet gas temperature shall not exceed the following:
 - minus twenty-five degrees Celsius (-25°C) when condensing VOC of vapor pressure greater than forty (40) kilo Pascals (five and eight-tenths (5.8) pounds per square inch);
 - minus fifteen degrees Celsius (-15°C) when condensing VOC of vapor pressure greater than twenty (20) kilo Pascals (two and nine-tenths (2.9) pounds per square inch);

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- zero degrees Celsius (0°C) when condensing VOC of vapor pressure greater than ten (10) kilo Pascals (one and five-tenths (1.5) pounds per square inch);
- (4) ten degrees Celsius (10°C) when condensing VOC of vapor pressure greater than seven (7) kilo Pascals (one (1) pounds per square inch); or
- (5) twenty -five degrees Celsius (25°C) when condensing VOC of vapor pressure greater than three and five-tenths (3.5) kilo Pascals (five-tenths (0.5) pounds per square inch).
- (b) Pursuant to 326 IAC 8-5-3(b)(1)(C), when using equivalent controls, the VOC emissions shall be reduced by at least as much as they would be by using a surface condenser which meets the requirements of conditions (a)(1) through (a)(5) as applicable. The approximate equivalent control efficiency for the RTO is 90%.
- (c) Pursuant to 326 IAC 8-5-3(b)(5) the Permittee shall install covers on all in process tanks that contain VOC's. These covers shall be kept closed unless production sampling, maintenance, or inspection procedures require operator access.
- (d) Pursuant to 326 IAC 8-5-3(b)(6) the Permittee shall repair all visible leaks from which a liquid, containing VOC can be observed running or dripping. The repair shall be completed the first time the equipment is off line for a period of time long enough to complete the repair.

Compliance Determination Requirements

D.1.2 Testing Requirements [326 IAC 2-7-6(1),(6)][326 IAC 2-1.1-11]

The Permittee is not required to test the facility by this permit. The testing required for this facility will be deferred and shall follow the schedule in the Title V Permit, to determine compliance with 326 IAC 8-5-3. However, IDEM may require compliance testing when necessary to determine if the facilities are in compliance. If testing is required by IDEM compliance with Condition D.1.1shall be determined by a performance test conducted in accordance with Section C -Performance Testing.

Compliance Monitoring Requirements [326 IAC 2-7-6(1)] [326 IAC 2-7-5(1)]

D.1.3 Monitoring For VOC Emissions

- (a) The VOC emissions from the proposed new process tanks (TK 40-11 and TK 53-10) shall be in compliance with 326 IAC 8-5-3 provided that:
 - (1) the Regenerative Thermal Oxidizers (RTO1 or RTO2) or Condensers (when Lilly elects to control the VOC by condensers) shall operate at all times the equipment being controlled are in operation and emitting VOC;
 - (2) when the VOC emissions from the proposed general process tanks are controlled by RTO1 and RTO2, the RTO's operating temperature shall be maintained at 1600°F, or the temperature determined during the most recent stack tests, to maintain at least 90% destruction of the volatile organic compounds. The operating temperature of the RTO shall be recorded and monitored continuously;

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(3) when the VOC emissions from the proposed general process tanks are controlled by the condensers, the outlet gas temperature shall be equal to or less than that specified by 326 IAC 8-5-3, see condition D.1.1;

- (4) the Permittee records the time during which the proposed process tanks were emitting VOC but the RTO or condensers, serving the proposed process tank, were not operated;
- (5) the Permittee records the reason the RTO or condensers were not operated;
- (6) the Permittee records the corrective actions taken to bring the RTO or condensers to normal operation; and
- (7) the Permittee records the number of hours the proposed process tanks, were emitting VOC and vented to points other than the RTO or a condenser complying with 326 IAC 8-5-3.

D.1.4 National Emission Standards for Hazardous Air Pollutants (NESHAPs) 40 CFR Part 63, Subparts I and H

That the owner or operator shall implement the Lilly Leak Detection and Repair (LDAR) Program, most recently approved by the Office of Air Management, to reduce fugitive emissions from processes that use methylene chloride. If it is not feasible to either pressure test a group of fugitive sources or monitor a specific compound, then a written justification will be required for each source or compound exempted from testing. Any necessary adjustments to the procedures shall be submitted to the Office of Air Management for approval prior to implementation.

D.1.5 40 CFR Part 63, Subpart GGG (National Emissions Standard for Pharmaceutical Production)
 The new process tanks are subject to the National Emission Standards for Hazardous Air
 Pollutants 40 CFR Part 63, Subpart GGG (National Emissions Standard for Pharmaceutical Production) and shall be in compliance with this NESHAP by the compliance date.

General tank TK40-11 and charge tank TK53-10 do not constitute a new or reconstructed affected source under Subpart GGG, nor do they constitute a new or reconstructed pharmaceutical manufacturing process unit. Therefore, the existing source requirements of Subpart GGG will apply.

Eli Lilly and Company Lafayette, Indiana 47909

Source Modification No.: 157-12478-00006 Permit Reviewer: ERG/MP

Record Keeping and Reporting Requirements

Record Keeping Requirements D.1.6

- The Permittee shall maintain records as follows:
 - The malfunction report of the RTOs; and applicable malfunction reports when the (1) facility is emitting VOC, but not venting to the RTO;

Page 14 of 16

- Weekly records of the operating temperature of the RTOs during normal operation (2) when TK40-11 orTK 53-10 are emitting VOC.;
- The number of hours the proposed process tanks were vented to points other than (3) the RTO or the condenser.
- (b) All records shall be maintained in accordance with Section C - General Record Keeping Requirements, of this permit.

MALFUNCTION REPORT

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT OFFICE OF AIR MANAGEMENT FAX NUMBER - 317 233-5967

This form should only be used to report malfunctions applicable to Rule 326 IAC 1-6 and to qualify for the exemption under 326 IAC 1-6-4.

THIS FACILITY MEETS THE APPLICABILITY REQU			
PARTICULATE MATTER ?, 25 TONS/YEAR 25 TONS/YEAR VOC ?, 25 TONS/YEAR HY ?, 25 TONS/YEAR REDUCED SULFUR CO CARBON MONOXIDE ?, 10 TONS/YEAR A COMBINATION HAZARDOUS AIR POLLUTANT? ELEMENTAL LEAD ?, OR IS A SOURCE LIMALFUNCTIONING CONTROL EQUIPMENT OR PILIMITATION	R SULFUR DIOXIDE ?_ /DROGEN SULFIDE ?_ /DMPOUNDS ?, 25 NY SINGLE HAZARDO P, 1 TON/YEAR LE STED UNDER 326 IAC ROCESS EQUIPMENT (, 25 TONS/YEAR NITF , 25 TONS/YEAR TOT I TONS/YEAR FLUORIDES IUS AIR POLLUTANT ? IAD OR LEAD COMPOUNE 2-5.1-3(2) ? EMISSIO CAUSED EMISSIONS IN EXC	ROGEN OXIDES?, I'AL REDUCED SULFUR IS ?, 100 TONS/YEAR, 25 TONS/YEAR ANY OS MEASURED AS ONS FROM CESS OF APPLICABLE
THIS MALFUNCTION RESULTED IN A VIOLATION LIMIT OF			
THIS INCIDENT MEETS THE DEFINITION OF 'MAL			
THIS MALFUNCTION IS OR WILL BE LONGER TH.	()		
COMPANY:		PHONE NO. ()
LOCATION: (CITY AND COUNTY) PERMIT NO AFS PLANT ID:			
PERMIT NO AFS PLANT ID:	:/	AFS POINT ID:	INSP:
CONTROL/PROCESS DEVICE WHICH MALFUNC	TIONED AND REASON	<u> </u>	
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		20	_ /40//1 101
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PAGE 1 OF 2

Eli Lilly and Company Page 16 of 16 Lafayette, Indiana 47909 Source Modification No.: 157-12478-00006

Permit Reviewer: ERG/MP

Please note - This form should only be used to report malfunctions applicable to Rule 326 IAC 1-6 and to qualify for the exemption under 326 IAC 1-6-4.

326 IAC 1-6-1 Applicability of rule

Sec. 1. This rule applies to the owner or operator of any facility required to obtain a permit under 326 IAC 2-5.1 or 326 IAC 2-6.1.

326 IAC 1-2-39 "Malfunction" definition

If this item is checked on the front, please explain rationale:

Sec. 39. Any sudden, unavoidable failure of any air pollution control equipment, process, or combustion or process equipment to operate in a normal and usual manner.

*Essential services are interpreted to mean those operations, such as, the providing of electricity by power plants. Continued operation solely for the economic benefit of the owner or operator shall not be sufficient reason why a facility cannot be shutdown during a control equipment shutdown.

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Indiana Department of Environmental Management Office of Air Management

Addendum to the Technical Support Document for a Part 70 Significant Source Modification

Source Background and Description

Source Name: Eli Lilly and Company

Source Location: 1650 Lilly Road, Lafayette, Indiana 47909

County: Tippecanoe
SIC Code: 2834 and 2879
Operation Permit No.: 157-6879-00006
Operation Permit Issuance Date: not yet issued
Permit Modification No.: 157-12478-00006

Permit Reviewer: ERG/MP

On October 14, 2000, the Office of Air Management (OAM) had a notice published in the The Journal & Courier, Lafayette, Indiana, stating that Eli Lilly and Company had applied for a Part 70 significant source modification relating to the construction of one 1,000 gallon general process tank and one 500 gallon charging tank. The notice also stated that OAM proposed to issue a permit for this operation and provided information on how the public could review the proposed permit and other documentation. Finally, the notice informed interested parties that there was a period of thirty (30) days to provide comments on whether or not this permit should be issued as proposed.

On November 8, 2000, Eli Lilly and Company submitted comments on the proposed Part 70 significant source modification. The summary of the comments is as follows:

Condition A.1

Comment 1: Change first sentence to "The Permittee owns and operates a stationary source that produces pharmaceutical products."

Response 1: The permit has been changed as follows:

A.1 General Information [326 IAC 2-7-4(c)] [326 IAC 2-7-5(15)]

The Permittee owns and operates a stationary **source that produces** pharmaceutical **products** manufacturing plant.

Comment 2: Remove the reference to responsible official as it is not required by the rules.

Response 2: The responsible official is needed in order to provide a contact name at the source. The responsible official has not been removed from Section A.1.

Condition A.2

Comment 3: Revise to read as follows: "...VOC emissions. CO emissions will be controlled voluntarily by existing RTOs. NOx and SO2 emissions will be controlled voluntarily by scrubbers.

Lafayette, Indiana Reviewer: ERG/MP

Response 3: The permit has been changed as follows:

Emissions units and Pollution Control Equipment Summary

This stationary source is approved to construct and operate the following emissions units and pollution control devices:

One (1) 1,000 gallon general process tank, designated as TK 40-11, located in an existing (a) building designated as T27, and capable of being controlled by the existing Regenerative Thermal Oxidizer (RTO) or condenser for VOC emissions. CO, NO., and SO. emissions will be controlled voluntarily by existing RTOs. NOx and SO2 emissions will be controlled voluntarily by and scrubbers (as appropriate).

Comment 4: Add the following paragraph after paragraph (b) to be consistent with previous permits.

"The point source emissions from the process vessels may vent directly to RTO1 or RTO2, or they may first vent to scrubbers, process control condensers, vacuum sources, or through other process vessels before going to the RTO. If venting the process vessels to the RTO would cause a safety concern, the process vessels may vent to an alternative pollution control device that complies with 326 IAC 8-5-3.

Response 4: The permit has been changed to include the paragraph above to follow A.2 (b).

Condition A.3

Comment 5: Revise opening sentence to read as follows, "This stationary source has submitted a Part 70 permit application TV157-6879-00006 on October 6, 1996, pursuant to 326 IAC 2-7-2 (Applicability) because:"

Response 5: The permit has been changed as follows:

Part 70 Permit Applicability [326 IAC 2-7-2] A.3

This stationary source has submitted is required to have a Part 70 permit application TV 157-6879-00006 on October 6, 1996, pursuant to by 326 IAC 2-7-2 (Applicability) because:

Condition B.4

Comment 6: Delete "However, in the event...after EPA review." And replace with "This significant source modification approval shall be incorporated into the Permitee's Part 70 permit application."

Response 6: Condition B.4 has been revised as follows:

B.4 Significant Source Modification [326 IAC 2-7-10.5(h)]

This document shall also become the approval to operate pursuant to 326 IAC 2-7-10.5(h) when, prior to start of operation, the following requirements are met:

(a) The attached affidavit of construction shall be submitted to the Office of Air Management (OAM), Permit Administration & Development Section, verifying that the emission units were constructed as proposed in the application. The emissions units covered in the Significant Source Modification approval may begin operating on the date the affidavit of construction is postmarked or hand delivered to IDEM if constructed as proposed.

- (b) If actual construction of the emissions units differs from the construction proposed in the application, the source may not begin operation until the source modification has been revised pursuant to 326 IAC 2-7-11 or 326 IAC 2-7-12 and an Operation Permit Validation Letter is issued.
- (c) If construction is completed in phases; i.e., the entire construction is not done continuously, a separate affidavit must be submitted for each phase of construction. Any permit conditions associated with operation start up dates such as stack testing for New Source Performance Standards (NSPS) shall be applicable to each individual phase.
- (d) The Permittee shall receive an Operation Permit Validation Letter from the Chief of the Permit Administration & Development Section and attach it to this document.

However, in the event that the Title V application is being processed at the same time as this application, the following additional procedures shall be followed for obtaining the right to operate:

- (1) If the Title V draft permit has not gone on public notice, then the change/addition covered by the Significant Source Modification will be included in the Title V draft.
- (2) If the Title V permit has gone thru final EPA proposal and would be issued ahead of the Significant Source Modification, the Significant Source Modification will go thru a concurrent 45 day EPA review. Then the Significant Source Modification will be incorporated into the final Title V permit at the time of issuance.
- (3) If the Title V permit has not gone thru final EPA review and would be issued after the Significant Source Modification is issued, then the Modification would be added to the proposed Title V permit, and the Title V permit will issued after EPA review.

This Significant Source Modification approval shall be incorporated into the Permitee's Part 70 Operating Permit.

Condition C.1

Comments 7 and 8: Delete paragraph C.1 entirely because certifications by responsible officials are Title V permit requirements and Lilly does not have a Title V permit yet. Therefore, these requirements do not apply to Lilly at this time. If comment 7 is not accepted, then change paragraph C.1 (b) to read,

"b) One (1) certification shall be included, on the attached Certification Form, with each submittal where certification is required by the terms of the applicable rule or specifically designated by this approval."

Response 7 and 8: The permit has been changed as follows:

C.1 Certification [326 IAC 2-7-4(f)][326 IAC 2-7-6(1)][326 IAC 2-7-5(3)(C)]

(a) Where specifically designated by this approval or required by an applicable requirement, any application form, report, or compliance certification submitted under this approval shall contain certification by a responsible official of truth, accuracy, and completeness. This certification, shall state that, based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate, and complete.

> (b) One (1) certification shall be included, on the attached Certification Form, with each submittal where certification is required by the terms of the applicable rule or specifically designated by this approval.

Condition C.2

Comment 9: Delete the following per previous permits and appeals, "...IDEM, OAM may require the Permittee to revise its Preventative Maintenance Plan whenever lack of proper maintenance causes or contributes to any violation."

Response 9: The issue regarding this condition has not been finally decided. IDEM recognizes this comment by the company. Until this issue is decided, this condition will remain.

Condition C.3

Comment 10: Per previous appeals on other permits, Condition C3 should be revised in the caption and subsection (a) to include a reference to 326 IAC 2-7-10.5. As currently written, Condition C.2. is not an accurate statement of the law. Presently, the Tippecanoe facility is a Part 70 source but has not yet received a Title V permit. Accordingly, to amend or modify this approval (due to a modification of the emission unit covered by this SSMA), Lilly must comply with 326 IAC 2-7-10.5.

Response 10: The issue regarding this condition has not been finally decided. IDEM recognizes this comment by the company. Until this issue is decided, this condition will remain.

Comment 11: Delete reference to responsible official, "Any such application should be certified by the "responsible official" as defined by 326 IAC 2-7-1 (34) only if a certification is required by the terms of the applicable rule." Delete paragraph C.3 (c) since 2-7-10.5 applies.

Response 11: Eli Lilly has commented on these conditions on recent approvals. However, as with the recent approvals (157-12124-00006 for example) the issues regarding these conditions have not been finally decided. IDEM recognizes this comment by the company. Until a resolution to these concerns is decided, these conditions will remain.

Condition C.4

Comment 12: Delete paragraph C.4 because the RTO is the emitting source and it has an opacity requirement.

Response 12: The RTO is still required to comply with the opacity requirements when controlling emissions from the new tanks. Therefore, this condition will remain.

Condition C.7

Comment 13: Make editorial changes suggested in the strikeout version of the permit.

Response 13: For new equipment installed, IDEM believes that the monitoring and record keeping requirements should be followed from the startup of the operation. Therefore, this condition will remain unchanged.

Condition C.8

Comment 14: Delete paragraph C.8 as these conditions are in excess of IDEM's regulatory and statutory authority. This condition has been appealed on previous permits.

Response 14: The issue regarding this condition has not been finally decided. IDEM recognizes this comment by the company. Until this issue is decided, this condition will remain.

Condition C.9 (b)

Comment 15: Delete sentence at end of paragraph ("Failure of the...affected facility.") because it is in excess of IDEM's authority. This sentence has been appealed on previous permits.

Response 15: The issue regarding this condition has not been finally decided. IDEM recognizes this comment by the company. Until this issue is decided, this condition will remain.

Condition C.10 (a) & (c)

Comment 16: Change wording to that in the strikeout section for clarification purposes.

Response 16: The permit has been changed as follows:

C.10 Monitoring Data Availability [326 IAC 2-7-6(1)] [326 IAC 2-7-5(3)]

- (a) With the exception of performance tests conducted in accordance with Section C-Performance Testing, all observations, sampling, maintenance procedures, and record keeping, required as a condition of this approval shall be performed at all times the equipment listed in Section D.1 is operating at normal representative conditions and is emitting a pollutant for which the approval requires emission controls is operating at normal representative conditions.
- (b) As an alternative to the observations, sampling, maintenance procedures, and record keeping of subsection (a) above, when the equipment listed in Section D of this approval is not operating, the Permittee shall either record the fact that the equipment is shut down or perform the observations, sampling, maintenance procedures, and record keeping that would otherwise be required by this approval.
- (c) If the equipment **listed in Section D** is operating but abnormal conditions prevail, **which may increase emissions of a pollutant for which the approval requires emission control**, additional observations and sampling should be taken with a record made of the nature of the abnormality.

Condition C.11 (c) (4)

Comment 17: Revise to read as follows. "Records of preventative maintenance shall ... indicate who performed the tasks."

Response 17: The issue regarding this condition has not been finally decided. IDEM recognizes this comment by the company. Until this issue is decided, this condition will remain.

Condition C.11 (d)

Comment 18: Replace "..upon startup." with "...within 90 days after operations begin."

Response 18: For new equipment installed, IDEM believes that the monitoring and record keeping requirements should be followed from the startup of the operation. Therefore, this condition will remain unchanged.

Reviewer: ERG/MP

Section D.1 Facility Description

Comment 19: Delete reference to HCl for consistency with previous permits and change wording per the attached strikeout section.

Response 19: The permit has been changed as follows:

(a) One (1) 1,000 gallon general process tank, designated as TK 40-11, located in an existing building designated as T27, and capable of being controlled by the existing Regenerative Thermal Oxidizer (RTO) or condenser for VOC emissions. HCl, CO, NO_x, and SO₂-emissions will be controlled voluntarily by existing RTOs. NOx and SO2 emissions will be controlled voluntarily by and scrubbers (as appropriate).

Section D.1.1

Comment 20: Make editorial and clarification changes per the attached strikeout section.

Response 20: The permit has been changed as follows:

D.1.1 Miscellaneous Operation: Synthesized Pharmaceutical Manufacturing [326 IAC 8-5-3]

(a) Pursuant to 326 IAC 8-5-3 when using condensers to control the VOC emissions from these process tanks the following outlet gas temperature when using condensers to control the VOC emissions from these process tanks including the existing facilities at the plant shall not exceed the following:

Section D.1.3

Comment 21: Make editorial and clarification changes per the attached strikeout section.

Response 21: The permit has been changed as follows:

D.1.3 Monitoring For VOC Emissions

- (a) The VOC emissions from the proposed new process tanks (TK 40-11 and TK 53-10) shall be in compliance with 326 IAC 8-5-3 provided that:
 - (1) the Regenerative Thermal Oxidizers (RTO1 or RTO2) or Condensers (when Lilly elects to control the VOC by condensers) shall operate at all times the equipment being controlled are in operation and emitting VOC;
 - when the VOC emissions from the proposed general process tanks including the existing facilities—are controlled by the RTO1 and RTO2, the RTO's operating temperature shall be maintained at 1600°F, or the temperature determined during the most recent stack tests, to maintain at least 90% destruction of the volatile organic compounds. The operating temperature of the RTO shall be recorded and monitored continuously;
 - when the VOC emissions from the proposed general process tanks including the existing facilities are controlled by the condensers, the outlet gas temperature shall be equal to or less than that specified by 326 IAC 8-5-3, see condition D.1.1;

- the Permittee records the time during which the **proposed process tanks were emitting VOC but** the RTO or condensers, serving the proposed process tank,
 including the existing facilities, were not operated;
- (5) the Permittee records the reason the RTO or condensers were not operated;
- (6) the Permittee records the corrective actions taken to bring the RTO or condensers to normal operation; and
- the Permittee records the number of hours the proposed process tanks, were emitting VOC and, including the existing facilities were vented to points other than the RTO or a condenser complying with 326 IAC 8-5-3.

Section D.1.5

Comment 22: Make editorial and clarification changes per the attached strikeout section.

Response 22: The permit has been changed as follows:

D.1.5 40 CFR Part 63, Subpart GGG (National Emissions Standard for Pharmaceutical Production)

The new process tanks are subject to **the National Emission Standards for Hazardous Air Pollutants** 40 CFR Part 63, Subpart GGG (National Emissions Standard for Pharmaceutical Production) and shall be in compliance with this NESHAP by the compliance date.

General tank TK40-11 and charge tank TK53-10 do not constitute a new or reconstructed affected source under Subpart GGG, nor do they constitute a new or reconstructed pharmaceutical manufacturing process unit. Therefore, the existing source requirements of Subpart GGG will apply.

Section D.1.6 (Malfunction Condition)

Comment 23: Delete paragraph entirely to be consistent with other SSMAs.

Response 23: The condition has been deleted from the permit.

Section D.1.7

Comment 24: Make editorial and clarification changes per the attached strikeout section.

Response 24: The permit has been changed as follows:

D.1.67 Record Keeping Requirements

- (a) The Permittee shall maintain records in accordance with (1) through (3) as follows:
 - (1) The malfunction report of the RTOs; and other applicable malfunction reports of the facilities when the RTO is operating but the facility is when the facility is emitting VOC, but not venting to the RTO;
 - (2) The RTO's operating temperature Weekly records of the operating temperature of the RTOs during normal operation when TK40-11 orTK 53-10 are emitting VOC.;

Eli Lily and Company Page 8 of 8 Lafayette, Indiana SPR-157-12478-00006

Lafayette, Indiana Reviewer: ERG/MP

(3) The number of hours the proposed process tanks including existing facilities were vented to points other than the RTO or the condenser; and.

Part 70 Source Modification Certification

Comment 25: Remove form (page 18 of 19) because there is not a requirement for "responsible person" certifications for an SSMA at a source without a Title V permit.

Response 25: The source is not subject to 326 IAC 2-7-4(f) or 326 IAC 2-7-5(3)(C), therefore the part 70 Source Modification Certification form has been deleted from the permit.

Technical Support Document

Comment 26: Make editorial and clarification changes per the attached strikeout section

Response 26: The Technical Support Document is not amended as part of the final permit approval issuance. Those editorial/clarification changes that affect the content of the permit have been incorporated into the final permit as indicated above.

Indiana Department of Environmental Management Office of Air Management

Technical Support Document (TSD) for a Part 70 Significant Source Modification.

Source Background and Description

Source Name: Eli Lilly and Company

Source Location: 1650 Lilly Road, LaFayette, Indiana 47909

County: Tippecanoe
SIC Code: 2834 and 2879
Operation Permit No.: 157-6879-00006
Operation Permit Issuance Date: not yet issued
Significant Source Modification No.: 157-12478-00006

Permit Reviewer: ERG/MP

The Office of Air Management (OAM) has reviewed a modification application from Eli Lilly and Company relating to the construction of the following emission units and pollution control devices:

- (a) One (1) 1,000 gallon general process tank, designated as TK 40-11, located in an existing building designated as T27, and capable of being controlled by the existing Regenerative Thermal Oxidizer (RTO) or condenser for VOC emissions. CO, NOx, and SO2 emissions will be controlled voluntarily by existing RTOs and scrubbers (as appropriate).
- (b) One (1) 500 gallon charging tank, designated as TK 53-10, located in an existing building designated as T27, and capable of being controlled by the existing Regenerative Thermal Oxidizer (RTO) or condenser for VOC emissions.

History

On July 7, 2000, Eli Lilly and Company, submitted an application to the OAM requesting to add two new tanks to their existing plant. Eli Lilly and Company submitted a Part 70 permit application (T157-6879-00006) on October 10, 1996.

Enforcement Issue

There are no enforcement actions pending.

Stack Summary

Stack ID	Height (feet)	Diameter (feet)	Flow Rate (acfm)	Temperature (°F)
RT01	125	9	98,000	170
or RT02	125	9	98,000	125

Recommendation

The staff recommends to the Commissioner that the Part 70 Significant Source Modification be approved. This recommendation is based on the following facts and conditions:

Unless otherwise stated, information used in this review was derived from the application and additional information submitted by the applicant.

An application for the purposes of this review was received on July 7, 2000.

Emission Calculations

The calculations submitted by the applicant have been verified and found to be accurate and correct. These calculations are provided in Appendix A of this document (17 pages).

Potential To Emit of Modification

Pursuant to 326 IAC 2-1.1-1(16), Potential to Emit is defined as "the maximum capacity of a stationary source to emit any air pollutant under its physical and operational design. Any physical or operational limitation on the capacity of a source to emit an air pollutant, including air pollution control equipment and restrictions on hours of operation or type or amount of material combusted, stored, or processed shall be treated as part of its design if the limitation is enforceable by the U.S. EPA."

This table reflects the PTE before controls. Control equipment is not considered federally enforceable until it has been required in a federally enforceable permit.

Pollutant	Potential To Emit (tons/year)
PM	0.0
PM-10	0.0
SO ₂	30.3
VOC	23.5
CO	19.77
NO _x	1.7

HAP's	Potential To Emit (tons/year)
HCI (gas)	17.8
TOTAL	17.8

Justification for Modification

The Part 70 Operating permit is being modified through a Part 70 Significant Source Modification. This modification is being performed pursuant to 326 IAC 2-7-10.5 (f)(4)(B) because the potential to emit (PTE) of SOx is greater than twenty-five(25) tons per year.

County Attainment Status

The source is located in Tippecanoe County.

Pollutant	Status
PM-10	attainment
SO ₂	attainment
NO ₂	attainment
Ozone	attainment
CO	attainment
Lead	attainment

- (a) Volatile organic compounds (VOC) and oxides of nitrogen (NOx) are precursors for the formation of ozone. Therefore, VOC and NOx emissions are considered when evaluating the rule applicability relating to the ozone standards. Tippecanoe County has been designated as attainment or unclassifiable for ozone. Therefore, VOC and NOx emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2 and 40 CFR 52.21.
- (b) Tippecanoe County has been classified as attainment or unclassifiable for SOx. Therefore, these emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2 and 40 CFR 52.21.

Source Status

Existing Source PSD or Emission Offset Definition (emissions after controls, based upon 8760 hours of operation per year at rated capacity and/or as otherwise limited):

Pollutant	Emissions (tons/yr)
PM	682.1
PM-10	682.1
SO ₂	5,626
VOC	5,351
CO	363
NO _x	2,834

- (a) This existing source is a major stationary source because an attainment regulated pollutant is emitted at a rate of 100 tons per year or more, and it is one of the 28 listed source categories.
- (b) These emissions are based upon AIRS Facility Quick Look Report, updated January 22, 1999.

Potential to Emit of Modification After Issuance

The table below summarizes the potential to emit, reflecting all limits, of the significant emission units after controls. The control equipment is considered federally enforceable only after issuance of this Part 70 source modification.

	Potential to Emit (tons/year)									
Process/facility	PM	PM-10	SO ₂	VOC	СО	NO _X	TRS	H₂S	Red. Sulfur	HAPs*
Tanks TK 40-11 and TK 53-10	0.0	0.0	30.3	2.5	19.77	1.7	0	0	0	0.9
Net Emissions	0.0	0.0	30.3	2.5	19.77	1.7	0	0	0	0.9
PSD Significant Levels	2.5	15	40	40	100	40	10	10	10	

Note:* = HCI (gas). These estimates reflect a 95% voluntarily control level achieved through the use of existing scrubbers.

This modification to an existing major stationary source is not major because the emission increase is less than the PSD significant levels. Therefore, pursuant to 326 IAC 2-2, and 40 CFR 52.21, the PSD requirements do not apply.

Federal Rule Applicability

- (a) (I) The tanks are not subject to New Source Performance Standard, 326 IAC 12, (40 CFR Part 60.110b, Subpart Kb Standards of Performance for Volatile Organic Liquid Storage Vessels), because they are not used for VOC storage purposes.
 - (ii) The tanks are not subject to New Source Performance Standard, 326 IAC 12, (40 CFR Part 60.480, Subpart VV Standards of Performance for Equipment Leaks of VOC in the Synthetic Organic Chemical Manufacturing Industry (SOCMI)), because they have a design capacity less than 1000 Mg/year.
 - (iii) The tanks are not subject to New Source Performance Standard, 326 IAC 12, (40 CFR Part 60.610, Subpart III, Standards of Performance for Volatile Organic Compounds (VOC) Emissions from Synthetic Organic Chemical Manufacturing Industry (SOCMI) Air Oxidation Unit Processes), because they are not air oxidation units.
 - (iv) The tanks are not subject to New Source Performance Standard, 326 IAC 12, (40 CFR Part 60.660, Subpart NNN, Standards of Performance for Volatile Organic Compounds (VOC) Emissions from Synthetic Organic Chemical Manufacturing Industry (SOCMI) Distillation Operations), because they are operated as batch reactors.
 - (v) The tanks are not subject to New Source Performance Standard, 326 IAC 12, (40 CFR Part 60.700, Subpart RRR, Standards of Performance for Volatile Organic Compounds (VOC) Emissions from Synthetic Organic Chemical Manufacturing Industry (SOCMI) Reactor Processes), because they are operated as batch reactors.

- (b) (I) The tanks are subject to National Emission Standards for Hazardous Air Pollutants(NESHAP), 326 IAC 14,(40 CFR 63.190(b)(5), Subpart H and I (40 CFR Part 63, Subpart H National Emission Standards for Organic Hazardous Air Pollutants for Equipment Leaks and 40 CFR Part 63, Subpart I -National Emission Standards for Organic Hazardous Air Pollutants for Certain Processes. Subject to the Negotiated Regulation for Equipment Leaks) when Methylene Chloride is used in them for pharmaceutical synthesis operations. Eli Lilly will comply with these requirements, with the implementation of Eli Lilly's LDAR program, when Methylene Chloride is used in the tanks.
 - (ii) The proposed process tanks are regulated under 40 CFR Part 63, Subpart GGG -National Emission Standards for Hazardous Air Pollutants for Pharmaceutical Production, which was promulgated on September 21, 1998. These process tanks shall be in compliance with this NESHAP no later than the compliance date, October 21, 2002.

State Rule Applicability - Individual Facilities

326 IAC 2-4.1 (New Source Toxics Control)

326 IAC 2-4.1 (New Source Toxics Control) does not apply to this facility as it is subject to 40 CFR Part 63 Subparts I, H, and GGG.

326 IAC 7 (Sulfur Dioxide Emission Limitation)

The process tanks have the potential to emit more than twenty-five (25) tons per year or ten (10) pounds per hour of sulfur dioxide. However, there are no applicable limits for the operations conducted in these tanks. Therefore, 326 IAC 7 does not apply.

326 IAC 8-5-3 (Miscellaneous Operation: Synthesized Pharmaceutical Manufacturing Operations)
This rule applies to the manufacture of pharmaceutical products by chemical synthesis. This section applies to all facilities emitting volatile organic compounds, including reactors, distillation units, dryers, storage of organic compounds, transfer of organic compounds, extraction equipment, filters, crystallizers, and centrifuges that have the potential to emit 15 pounds per day or more. The sections that are applicable to Lilly are (b)(1), (5) and (6).

Section (b)(1) of this rule requires that the VOC emissions coming from all reactors, distillation operation, crystallizers, centrifuges, and vacuum dryers shall be controlled by condensers or equivalent controls. The approximate control efficiency required by 326 IAC 8-5-3(b)(1) when using acetone, which has the worst volatility is around 90%.

Lilly is in compliance with this section of the rule, controlling the VOC emissions using either condensers in series with the Regenerative Thermal Oxidizer (RTO), or using the RTO alone. Lilly typically uses the existing RTO to control point source VOC emission from the tanks. The RTO, which has been demonstrated to achieve VOC removal efficiency in excess of 97%, will meet and exceed the requirement of the rule. If the RTO cannot be used due to safety issues, an alterative control device may be used. An analysis to demonstrate the alternative controls are equivalent controls will be done before they are used. Lilly would like to continue manufacturing operations in the process vessels included in this application using other existing pollution control equipment that complies with 326 IAC 8-5-3.

Section(b)(5) of this rule requires the owner or operator to install covers on all in process tanks that contain VOC's. Lilly complies with this section by using covers on all in process tanks, these covers are closed unless production sampling, maintenance, or inspection procedures require operator access.

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Section (b)(6) of this rule requires the owner or operator to repair all visible leaks containing VOC. The repair shall be completed the first time the equipment is off line for a period of time long enough to complete the repair.

Compliance Requirements

Permits issued under 326 IAC 2-7 are required to ensure that sources can demonstrate compliance with applicable state and federal rules on a more or less continuous basis. All state and federal rules contain compliance provisions, however, these provisions do not always fulfill the requirement for a more or less continuous demonstration. When this occurs IDEM, OAM, in conjunction with the source, must develop specific conditions to satisfy 326 IAC 2-7-5. As a result, compliance requirements are divided into two sections: Compliance Determination Requirements and Compliance Monitoring Requirements.

Compliance Determination Requirements in Section D of the permit are those conditions that are found more or less directly within state and federal rules and the violation of which serves as grounds for enforcement action. If these conditions are not sufficient to demonstrate continuous compliance, they will be supplemented with Compliance Monitoring Requirements, also Section D of the permit. Unlike Compliance Determination Requirements, failure to meet Compliance Monitoring conditions would serve as a trigger for corrective actions and not grounds for enforcement action. However, a violation in relation to a compliance monitoring condition will arise through a source's failure to take the appropriate corrective actions within a specific time period.

The compliance monitoring requirements applicable to this modification are as follows:

The process tanks TK 40-11 and TK 53-10 have applicable compliance monitoring conditions as specified below:

- (a) the Regenerative Thermal Oxidizers (RTO) or Condensers (when Lilly elects to control the VOC by condensers) shall operate at all times the equipment being controlled are in operation;
- (b) when the VOC emissions from the proposed general process tanks including the existing facilities are controlled by the RTO, the RTO's operating temperature shall be maintained at 1600°F, or the temperature determined during the most recent stack tests, to maintain at least 90% destruction of the volatile organic compounds. The operating temperature of the RTO shall be recorded and monitored continuously;
- (c) when the VOC emissions from the proposed general process tanks including the existing facilities are controlled by the condensers, the outlet gas temperature shall be equal to or less than that specified by 326 IAC 8-5-3;
- (d) the Permittee shall record the time during which the RTO or condensers, serving the proposed process tank, including the existing facilities, were not operated;
- (e) the Permittee shall record the reason the RTO or condensers were not operated;
- (f) the Permittee shall record the corrective actions taken to bring the RTO or condensers to normal operation;
- (g) the Permittee shall record the number of hours the proposed process tanks, including the existing facilities were vented to points other than the RTO or a condenser complying with 326 IAC 8-5-3;

- (h) The owner or operator shall implement the Lilly Leak Detection and Repair (LDAR) Program, most recently approved by the Office of Air Management, to reduce fugitive emissions from processes that use methylene chloride. If it is not feasible to either pressure test a group of fugitive sources or monitor a specific compound, then a written justification will be required for each source or compound exempted from testing. Any necessary adjustments to the procedures shall be submitted to the Office of Air Management for approval prior to implementation.
- (i) The new process tanks are subject to 40 CFR Part 63, Subpart GGG (National Emissions Standard for Pharmaceutical Production) and shall be in compliance with this NESHAP by the compliance date.

Conclusion

The construction of this proposed modification shall be subject to the conditions of the attached proposed Part 70 Significant Source Modification No. 157-12478-00006.

Emissions Calculations

Source Location: 1650 Lilly Road, Lafayette, Indiana 47909

County: Tippecanoe SIC Code: 2834 & 2879

Operation Permit No.: TV 157-6879-00006

Operation Permit Issuance Date: Pending

Minor Source Modification No.: 157-12478-00006

Permit Reviewer: ERG/MP

Eli Lilly and Company has submitted an application relating to the installation of new process tanks, identified as TK 40-11 and TK 53-10, both in building T27. The volatile organic compounds (VOC) emissions from these tanks will be controlled directly by the existing Regenerative Thermal Oxidizer (RTO) permitted under Construction Permit CP157-1980.

The point source emissions from these process vessels may vent directly to the RTO, or they may first vent to scrubbers, process control condensers, vacuum sources, or through other process vessels before going to the RTO. If venting the process vessel to the RTO would cause a safety concern, the process vessels may vent to an alternative pollution control device. Also, in the event that the RTO is unavailable, Lilly would continue manufacturing operations in the process vessels using other existing pollution control equipment that complies with 326 IAC 8-5-3. The carbon monoxide emissions from these replacement tanks will be voluntarily controlled by the RTOs. The sulfur dioxide emissions from these tanks will be voluntarily controlled by scrubbers. The nitrogen oxides emissions from these replacement tanks will be voluntarily controlled by scrubbers.

Potential emissions from these tanks are:

Potential to Emit (tons/year)						
Proposed Process Tanks	Capacity (Gallons)	VOC & Org. HAPs	со	SO ₂	NOx	Inorganic HAPs*
T27 Gen'l TK TK 40-11	1000	20.16	19.77	30.30	1.70	12.00
T27 Charge Tank TK 53-10	500	4.63				6.00
TOTAL		24.79	19.77	30.30	1.70	18.00

^{*} HCI (gas)

Process Description:

The process vessels can be used in a variety of operations involved in pharmaceutical manufacturing. These operations can be of batch or continuous nature and include, but are not limited to: heating, cooling, distilling (atmospheric and vacuum), extracting, crystallizing, chemical synthesis, cryogenic service, and their associated operations.

The process used to model the emissions from the general process vessels is a worst case process designed to give a maximum emissions estimate for any process that may be run in this piece of equipment. While general process vessels are only used in the production of bulk pharmaceutical drugs, the type of products manufactured will vary with the market demand.

Emissions calculations for point source VOC emissions from all tanks were performed by the applicant, using the equations found in the EPA guideline for control of volatile organic compounds emissions from manufacture of synthesized pharmaceutical products, EPA-450/2-78-029. To estimate the maximum potential uncontrolled and allowable VOC emissions for each piece of equipment, acetone was used as solvent in the emission calculations and 8760 hours/year operating schedule was assumed to get a worst case potential emissions scenario. Acetone although a non-photochemically reactive hydrocarbon, was used in the calculations because it has the highest volatility among the solvent utilized. Since solvents with vapor pressures as high as that of acetone are not always used in the processes, the assumption used in the calculations will generate a worst case estimate for the potential VOC emissions.

For this application, the VOC emissions estimate from all tanks is based on a combination of the typical unit operations that are done to perform a process. The process steps in the model for tanks include charging, heating, atmospheric and vacuum distillations. The process used to model the VOC emissions from the tanks is a worst case process designed to give a maximum emissions estimate for any process that may be run in the tank. For example, a distillation process can include a tank evacuation, a heating, and distillation steps.

The emission calculations assume the control device is a condenser with exit gas temperature of -15EC. This demonstrates that the control efficiency required to comply with 326 IAC 8-5-3 is approximately 90%. The RTO is designed to achieve more than 95% reduction of the VOC emissions which will meet the requirements of 326 IAC 8-5-3. When condensers are used to control VOC emissions, these condensers will achieve an efficiency of 90%. The various assumptions used in calculating emissions from different process activities may be found with the relevant equations in the sample calculations. For this application, the process tank VOC emission estimates are based on a combination of the typical unit operations that are done to perform a process. The steps in the model process include charging, heating, tank evacuation with vacuum distillations, and atmospheric distillations. For example, a distillation process can include a tank evacuation, a heating step, and a distillation step. For all processes, acetone a non-photochemically reactive hydrocarbon was used in the calculations, since it has the highest volatility among the solvent being utilized.

During distillation operations, the condenser on a process vessel is not considered to be a pollution device. It is classified as a process control device because it is vital to production of the normal product of the distillation. No other process operations will have condensers as the pollution control device.

The calculations for the controlled point source VOC emissions from the process tank assumes that the pollution control device is a condenser (exit gas temperature -15EC). The VOC emissions leaving the condensers are calculated assuming ideal liquid and vapor in equilibrium at a given temperature and pressure.

Potential uncontrolled fugitive emissions were estimated using SOCMI factors by the applicant (see attached spreadsheet).

Process Vessel VOC Calculation Assumptions:

- 1. Pure acetone used as the VOC in all calculations
- 2. The vessel contains perfectly mixed ideal liquid and vapor phases, and they are continuously in phase equilibrium.
- 3. The vapor leaving the vessel is assumed to have the same composition as the vapor in the tank's vapor space.

- 4. The streams leaving the condensers, where used, are calculated assuming ideal liquid and vapor in equilibrium at the given temperature and pressure.
- 5. It is assumed that the amount of liquid being vaporized in the tank is small when compared to the total liquid volume. Therefore, the liquid composition and the volume of the vapor space can be assumed to be constant.
- 6. The control device is a condenser that will produce an exit gas temperature of -15EC (per 326 IAC 8-5-3 for acetone)under all loading, or an equivalent control device that will have the same control efficiency as this condenser.
- 7. VOC emissions are from the tanks themselves, not ancillary existing equipment.
- 8. Nitrogen purge rate for inerting purposes is 5 scfh.
- 9. Charging into a tank is at 60 gallons per minute.
- 10. Tanks are charged 2/3 full of acetone for all tank sizes.
- 11. The tank is assumed to start each operation 2/3 full, except for "Charging" where the tank is empty at the start. The vapor space is assumed to be composed of gaseous N₂ in equilibrium with acetone vapor at the stated temperature.
- 12. The atmospheric distillation involves heating the tank contents (pure acetone) to its boiling point, then distilling over 1/2 of the liquid volume.
- 13. During the atmospheric distillation, there are two condensers. The first is a process control condenser that produces an exit gas temperature of 23EC(55EF cooling water = 12.78EC + 10EC approach = 22.78 ~ 23EC). The emissions from this condenser are listed in the potential uncontrolled column. The second is an emissions control condenser that produces an exit gas temperature of -15EC, or a control device with the same control efficiency. The emissions from this condenser are listed in the potential controlled column.
- 14. There is a 5 scfh nitrogen purge during all atmospheric distillations.
- 15. "Evacuation" means evacuating the tank from atmospheric pressure down to 1 mmHg above the vapor pressure of acetone at 20EC.
- 16. The vacuum distillation inert leak rate is 0.5 scfm for all tank sizes and vacuum levels. This is the average leak rate.
- 17. The vacuum distillation involves evacuating the tank from atmospheric pressure to acetone's vapor pressure at 20EC, then distilling over 1/2 of the liquid volume.
- 18. During the vacuum distillation, there are two condensers. The first is a process control condenser that produces an exit gas temperature of 0EC (-10EC brine + 10EC approach = 0EC). The emissions from this condenser are listed in the potential uncontrolled column. The second is an emissions control condenser that produces an exit gas temperature of -15EC, or a control device with the same control efficiency. The emissions from this condenser are listed in the allowable column.
- 19. The pressure transfer operation consists of pressuring-up the tank with nitrogen from 1 to 2 atmospheres to force the liquid out of the tank. When the tank is empty, this pressure is released from the tank.

- 20. There are no process condensers on the purge, charge, heat from 20EC to 55EC, evacuation, or de-pressurization steps. A condenser is not needed to perform these operations.
- It is assumed that during the time the tank is not performing a set of steps that it can be 21. doing another operation that the 24 hour sweep will account for that operation's emissions, i.e., stirring, cooling.
- "Per step" emissions are for performing the given step, or series of steps, once. 22.
- "Yearly" emissions are for performing the given step, or series of steps, once per day, 365 23. days per year.
- 24. For the sets of steps listed under "potential process chain for 1 day", each set is performed independently of the previous and next set of steps. The time required to perform each set of steps is also listed, then summed. It is also assumed that this process chain is only performed once per day.
- 25. These examples calculations are for a 2,000 gallon tank.

Calculation Nomenclature

Antoine coefficients a.b.c The ith. component i

K_{ideal} Vapor/liquid equilibrium constant Log mean pressure difference (mm Hg) LMPD Total moles in liquid phase (lb-mole) L

Moles of component i in liquid phase (lb-mole) L.

М Mass(lb)

M. Mass of component i (lb)

Mass rate (lb/hr) m

Mass rate of component i (lb/hr) m, Molecular weight (lb/lb-mole) MW

Molecular weight of component i (lb/lb-mole) MW,

N or V Total moles in vapor phase (lb-mole)

Molar rate (lb-mole/hr) n

Moles of component i in vapor phase (lb-mole) N_i or V_i

Molar rate of component i (lb-mole/hr)

P or P_{total} Total Pressure (mm Ha)

Ρi Partial pressure of component i (mm Hg)

 p^0 Vapor pressure (mm Hg)

 $p_{i}^{\,0}$ Vapor pressure of component i (mm Hg) Ideal Gas Constant (10.73 ft³ psia/lb-mole ⁰R) R Т Temperature in Kelvin (K) or Rankine(ER) Temperature in Celsius (EC) or Fahrenheit (EF) t

V Volume (ft³)

V or N Total moles in vapor phase (lb-mole)

V_i or N_i Moles of component i in vapor phase (lb-mole) Volumetric rate (gpm for liquid, cfm for vapor or gas)

Liquid mole fraction of component i X_i Vapor mole fraction of component i y_i Total moles entering condenser (lb-mole) Ζ

Total moles of component i entering condenser (lb-mole)

Sample calculations for VOC emissions:

```
Physical Properties:
```

Acetone:

```
Molecular weight = 58.08
Antoine Coefficients (-59.4EC to 56.5EC) a = 16.82 b = 2993 c = -35.63
Specific gravity @ 20EC = 0.792
```

Nitrogen(gaseous):

Molecular weight = 28

Possible Operation Step A: N₂ inerting purge @ 5 scfh

Tanks that contain a flammable liquid(s) or a VOC(s) are purged with gaseous N_2 to keep the vapor space above the liquid inert. As a continuous stream of N_2 flows into the tank, N_2 becomes saturated with vapor that is in equilibrium with the liquid. An emission is created as this N_2 /vapor mixture leaves the tank.

```
Liquid temperature = 293.15E K (20EC)
Vessel Pressure = 760 mm Hg
```

Pure acetone is in the tank during this step, so the mole fraction of liquid component (x_A) is 1.

Potential uncontrolled VOC emissions:

Vapor pressure calculation: Using the Antoine Equation at liquid temperature (20EC),

```
\begin{array}{lll} \mbox{ln(pA}^{\mbox{\scriptsize O}}) & = & \mbox{\scriptsize [a-(b/(T(^{\mbox{\tiny O}}K)+c)]} \\ \mbox{\scriptsize pA}^{\mbox{\tiny O}} \mbox{\scriptsize (mmHg)} & = & \mbox{\scriptsize exp} \mbox{\scriptsize [a-(b/(T(^{\mbox{\tiny O}}K)+c))]} \\ & = & \mbox{\scriptsize exp} \mbox{\scriptsize [16.82-(2993/(293.15-35.63)]} \\ & = & \mbox{\scriptsize 180.84 mmHg} \end{array}
```

Equilibrium Concentration: Raoult's Law states that the partial pressure of acetone, P_A , can be calculated by multiplying the vapor pressure, pA^O , by the liquid mole fraction, x_A , which equals the total pressure, P, multiplied by the vapor mole fraction, y^A .

$$(P)(y_A) = (pA^O)(x_A) = P_A$$

Rearranging yields:

$$y_A/x_A = pA^O/P = K_{ideal}$$

 $y_A = (K_{ideal})(x_A)$
 $= (180.84/760)(1)$
 $= 0.2379$

Inert Sweep Rate: It is assumed that the amount of N_2 entering the tank leaves the tank at the same rate. It is assumed that the N_2 stream enters the tank at 70EF (530°R) and 14.72 psia. Using the ideal gas law;

PV = nRT

PV = (m/MW)RT Since: n = m/MW

m = PV(MW)/RT

The mass flow rate, m, is:

$$\begin{array}{rcl} m_{n2} \, (\text{lb/hr}) & = & \frac{v(\text{cfh})(MW_{N2})(14.72 \, \text{psia})}{(R)(530^{\circ} R)} \\ \\ & = & \frac{(5 \, \text{scfh})(28)(14.72 \, \text{psia})}{(10.73)(530^{\circ} R)} \\ \\ & = & 0.3624 \end{array}$$

For 24 hours:

$$MN_2(lb) = (0.3624 lb/hr) (24 hrs) = 8.70 lb$$

Mass of acetone leaving the system: The number of moles of volatile components leaving the tank is related to the number of moles leaving the system and the partial pressure of the volatile and inert compounds. For a one component system:

$$(P_{\Delta})(v) = (n_{\Delta})(R)(T)$$

For the inert sweep, v, R, and T are assumed constant. Therefore, the ratio of moles of inert to volatile compounds can be calculated as:

The mass rate of acetone vapor emitted by the N₂ sweep is:

$$\begin{array}{ll} m_A(lb/hr) &= (M_{N2}/MW_{N2})(MW_A)(P_A/(P_A-P)) \\ &= (0.3624/28)(58.08)(180.84/(760-180.84)) \\ &= 0.2347 \ lb/hr \end{array}$$

For 24 hours:
$$M_A(lb) = (0.2347 lb/hr)(24 hrs)$$

= 5.63 lb

Maximum controlled VOC emissions (per 326 IAC 8-5-3):

Potential controlled emissions are based on emissions from the emission control device. In these calculations it is assumed to be a surface condenser that produces an exit vapor temperature of -15EC, to ensure compliance with 326 IAC 8-5-3 for acetone.

Vapor pressure calculation: Using the Antoine Equation at -15EC,

$$\begin{array}{ll} \text{ln (pAE(mmHg))} & = [a\text{-(b/(T(EK)+c))}] \\ \text{pAE(mmHg)} & = \exp \left[a\text{-(b/(T(EK)+c))}\right] \\ & = \exp \left[a\text{-(b/(T(EK)+c))}\right] \\ & = \exp \left[16.82 - (2993/(258.15 - 35.63)\right] \\ & = 29.06 \\ \text{K}_{\text{ideal}} = 29.06/760 & = 0.0382 \end{array}$$

The total number of moles entering the condenser is equal to the sum of the liquid and vapor moles leaving the condenser:

$$Z = V + L$$

Likewise for each component:

$$\begin{array}{lll} Z_i = V_i + L_i & \text{Where Li} = 0 \text{ for inert} \\ Z_i = (V)(y_i) + (L)(x_i) & \text{for volatile compounds} \\ Z_i = (V)(y_i) & \text{for inert compounds} \\ Z_i = (V)(K_{ideal})(x_i) + (L)(x_i) & \text{Since } K_{ideal} = y_i/x_i \\ Z_i/L = (V/L)(K_{ideal})(x_i) + (x_i) & \\ Z_i/L = [(V/L)(K_{ideal}) + 1] & \\ Z_i/[(V/L)(K_{ideal}) + 1] & \\ Z_i/[(V/L)(K_{ideal}) + 1] & \\ L_i = Z_i/[(V/L)(K_{ideal}) + 1] & \\ \end{array}$$

To solve the mass balance for the number of moles in the liquid and vapor phases:

- Assume a V/L ratio(where V is total molar volume including the inert gases)
- 2. Calculate the liquid moles of each volatile component by:

$$L_i = Z_i/[(V/L)(K_{ideal}) + 1]$$

3. Calculate the vapor moles of each volatile component by:

$$Vi = Z_i - L_i$$

- 4. The moles of inert out of the condenser is equal to the moles into the condenser, which has been calculated previously.
- 5. Sum the volatile component liquid moles (L) and the volatile and inert component vapor moles (V) and compute the ratio V/L.
- 6. The computed V/L is compared to the assumed V/L. If they are not equal, a new iteration is performed using the calculated V/L.

The following table shows the values used for the iteration:

		Calc	culated		
Iteration	Assumed V/L	LA	VA	VN2	Calculated V/L
1	0.50	0.0952	0.0018	0.3106	3.28
2	3.28	0.0862	0.0108	0.3106	3.73
3	3.73	0.0849	0.0121	0.3106	3.8
4	3.80	0.0847	0.0123	0.3106	3.81
5	3.81	0.0847	0.0123	0.3106	3.81

The mass of each component is related to its moles by:

```
M_i(lbs) = (V_i)(MW_i)

M_A(lbs) = (0.0123)(58.08)

= 0.71 lb
```

Possible operation Step B: Charge 2000 gallon tank 2/3 full:

This calculation models the emissions associated with the displacement of vapor from a tank that is being filled with a VOC. The tank in this case is filled 2/3 full with acetone at 20EC at 60 gallons per minute. The tank is assumed to be filled with gaseous N_2 before charging, and the displaced vapor is N_2 , 100% saturated with acetone.

```
Liquid temperature = 293.15K ( 20EC)
Tank pressure = 760 mmHg
```

Pure acetone is charged into the tank during this step, so the mole fraction of liquid component (x_{A}) is 1.

Potential VOC emissions:

Volume of charged material:

```
V_L = (2000 gallons)(2/3) = 1,333.33 gallons
= (2000 gal)(1ft<sup>3</sup>/7.4805 gal)(2/3) = 178.24 ft<sup>3</sup>
```

This is also the volume of inert being displaced.

Molar displacement rate of inert:

The volatile and inert vapor partial pressures are related by:

$$P_{Total} = P_A + P_{N2}$$

The partial pressure of N₂ is then:

```
P_{N2} = P_{Total} - P_{A}
= (760)- (180.84)
= 579.16 mmHg
= (579.16 mmHg)(14.696 psia/760 mmHg)
= 11.20 psia
```

Applying Dalton's Law:

$$n_{N2}$$
 = $(P_{N2})(V_{L})/[(R)(T)]$
= $(11.20 \text{ psia})(178.24 \text{ ft3})$
 $((10.73)(527.67))$
= 0.3526 lbmoles

Mass of Acetone leaving the tank:

The mass rate of acetone vapor emitted by the liquid displacement:

```
M_A(lb) = (M_{N2})(MW_A)(P_A/P_{N2})
= (0.3526)(58.08)(180.84)/(579.16)
= 6.39 lbs
```

Maximum controlled VOC emissions under rule 326 IAC 8-5-3:

Potential controlled VOC emissions are based on emissions from the control device. In these calculations it is assumed to be a surface condenser that produces an exit vapor temperature of -15EC. The total number of moles entering the condenser is equal to the sum of the liquid and vapor moles leaving the condenser. This calculation is identical in method to Step A's (N_2 inerting purge @ 5 scfh) Potential Controlled calculation method.

The resulting VA of the iterative calculation is: 0.0140

The mass of each component is related to its moles by:

```
M_i(lbs) = (V_i)(MW_i)

M_A(lbs) = (0.014)(58.08)

= 0.81 lbs
```

Possible operation Step C: Heat tank contents from 20EC to 55EC:

This calculation models the emissions associated with the displacement of vapor from acetone that is being heated from 20EC to 55EC. The vapor space above the liquid is assumed to consist of gaseous N_2 saturated with acetone vapor. As the liquid heats up, it vaporizes and displaces the vapor above it, causing an emission from the tank.

```
Initial liquid temperature = 293.15K (20EC, 527.67ER)
Final liquid temperature = 328.15K (55EC, 626.67ER)
Tank pressure = 760 mmHg
```

Volume of acetone in tank:

```
V_1 = (2000 gallons)(1 ft<sup>3</sup>/7.4805 gal)(2/3) = 178.24 ft<sup>3</sup>
```

Volume of vapor space:

$$V_{VS}$$
 = (2000 gallons)(1 ft³/7.4805 gal)(1/3) = 89.12 ft³

Pure acetone is in the tank during this step, so the mole fraction of liquid component (x_A)is 1.

Potential VOC emissions:

Vapor Pressures: Initial and final vapor pressures are calculated using the Antoine equations as previously shown.

Initial:

```
Acetone, pEA,I = 180.84 mmHg (3.50 psia) K_{ideal},I = 0.2379 Nitrogen, pEN<sub>2</sub>,I = 579.16 mmHg (11.20 psia)
```

Final:

Acetone, pEA,F = 726.49 mmHg (14.05 psia)
$$K_{ideal}$$
,F = 0.9559 Nitrogen, pEN₂,F = 33.51 mmHg (0.65 psia)

Change in moles of inert in vapor space between initial and final conditions:

$$\begin{aligned} NN_{2}, I - NN_{2}, F &= \frac{(P_{N2}, I)}{(T_{1})} - \frac{(P_{N2}, F)}{(T_{F})}] \text{ (VVS)/(R)} \\ &= \left[\frac{(11, 20)}{(527.67)} - \frac{(0.65)}{(626.67)} \right] \text{ (89.12)/(10.73)} \\ &= 0.1677 \text{ lbmoles} \end{aligned}$$

Amount of acetone being displaced from the tank:

The total number of moles in the vapor space and the vapor phase composition are both functions of temperature. Since the molar rate at which vapors leave the tank is greatly influenced by the components partial pressure, it is assumed that for any component:

$$N_i / (LMPD)_i = Constant$$

Where N_i is the number of moles of component i having left the tank.

The Log Mean Pressure Difference of i, (LMPD)i, is calculated as follows:

$$\begin{array}{ll} (LMPD)_i & = (P_i - P_F)i \ / \ ln(P_i/P_F)i \\ (LMPD)_A & = (180.84 - 726.49)_A \ / \ ln(180.84/726.49)_A \\ & = 392.38 \\ (LMPD)_{N2} & = (579.16 - 33.51)_{N2} \ / \ ln \ (579.16/33.15)_{N2} \\ & = 190.75 \end{array}$$

Therefore, the number of moles of acetone can be estimated by:

$$N_A = (N_{N2})(LMPD)_A / (LMPD)_{N2}$$

And the mass of acetone leaving the tank is:

$$M_A$$
 (lbs) = $(N_{N2})[(LMPD)_A / (LMPD)_{N2}](MW_A)$
= $(0.1677)[(392.38)/(190.75)](58.08)$
= 20.04 lb

Maximum Controlled VOC Emissions (under 326 IAC 8-5-3):

Potential controlled VOC emissions are based on emissions from the control device. In these calculations it is assumed to be a surface condenser that produces an exit vapor temperature of -15EC.

The total number of moles entering the condenser is equal to the sum of the liquid and vapor moles leaving the condenser. This calculation is identical in method to Step A's (N₂ inerting purge @ 5 scfh) Potential controlled calculation method.

The resulting V_A of the iterative calculation is: 0.0067

The mass of each component is related to its moles by:

```
M_i (lbs) = (V_i)(MW_i)

M_A (lbs) = (0.0067)(58.08)

= 0.39 lbs
```

Possible Operation Step D: Atmospheric Distillation

The atmospheric distillation involves heating the tank contents (pure acetone) to its boiling point, then distilling over 1/2 of the liquid volume. During the atmospheric distillations, there are two condensers. The first is a process control condenser that produces an exit gas temperature of 23EC (55EF cooling water = 12.78EC + 10EC approach = 22.78EC ~ 23EC). The second is an emission control condenser that produces an exit gas temperature of -15EC, or a control device with the same control efficiency.

Heating acetone to its boiling point is modeled using the method outlined in Step C (Heat tank contents from 20EC to 55EC). The distillation is modeled using the method outlined in Step A (N_2 inerting purge @ 5 scfh) with an additional "potential controlled emissions" calculation because there are two condensers as explained above.

Possible Operation Steps E & F: Vacuum Distillation

The Vacuum distillation involves evacuating the tank from atmospheric pressure to acetone's vapor pressure at 20EC , then distilling over 1/2 of the liquid volume. Because the system is under vacuum, and it is not perfectly sealed, air leaks into the system. During the vacuum distillation, there are two condensers. The first is a process control condenser that produces an exit gas temperature of 0EC (-10EC brine + 10EC approach = 0EC). The second is an emission control condenser that produces an exit gas temperature of -15EC, or a control device with the same control efficiency.

Evacuating the tank to acetone's boiling point (at 20EC) is modeled using the method outlined below. The air leakage during the distillation is modeled using the method outlined in Step A (N_2 inerting purge @ 5 scfh) with an additional "potential controlled emissions" calculation because there are two condensers as explained above.

```
Liquid temperature = 293.15 K (20EC, 527.67ER)
Initial tank pressure = 760 mmHg
```

Volume of acetone in tank:

```
V_L = (2000 gallons)(2/3) = 1,333.33 gallons
= (2000 gallons)(1 ft<sup>3</sup>/7.4805 gallons)(2/3) = 178.24 ft<sup>3</sup>
```

Volume of vapor space:

```
V_{VS} = (2000 gallons)(1/3) = 666.67 gallons
= (2000 gallons)(1 ft<sup>3</sup>/7.4805 gallons)(1/3) = 89.12 ft<sup>3</sup>
```

Pure acetone is in the tank during this step, so the mole fraction of liquid component (X_{Δ}) is 1.

Potential VOC emissions:

Vapor Pressures: Calculated using the Antoine equations as previously shown.

Initial:

```
Acetone, p^0A,I = 180.84 mmHg K_{ideal},A = 0.2379 Nitrogen, p^0N_2,I = 579.16 mmHg
```

Mass of N_2 evacuated from tank: Since the vapor pressures of acetone and N_2 are constant, as well as the vapor space and temperature, the moles of acetone also remain constant, i.e., as any acetone vapor leaves the system, it is replaced by an equal amount from the liquid phases. The decrease in pressure, therefore, is due to the evacuation of N_2 . The number of moles of N_2 leaving the system are calculated by:

$$(N_{N2},Initial - N_{N2},Final) = (P_{Initial} - P_{Final})(V_{VS})/[(R)(T)]$$

= $\frac{(14.696 - 3.5)(89.12)}{(10.73)(527.67)}$
= 0.1762 lbmoles

Mass of Volatiles evacuated from tank: Using the LMPD method as described in Step C (Heat tank contents from 20EC to 55EC) the mass of acetone leaving the tank is calculated by:

```
 \begin{array}{ll} (LMPD)N_2 & = (P_1 - P_F)N_2 / \ln(P_1/P_F)N_2 \\ (LMPD)N_2 & = (579.16 - 0.16)N_2 / \ln(579.16/0.16)N_2 \\ & = 70.66 \\ M_A \text{ (Ibs)} & = [(N_{N2})/(LMPD)N_2](MW_A)(P_A) \\ & = [(0.1762)/(70.66)](58.08)(180.84) \\ & = 26.19 \text{ lb} \\ \end{array}
```

Maximum Controlled VOC Emissions (under 326 IAC 8-5-3):

Potential controlled emissions are based on emissions from the control device. In these calculations it is assumed to be a surface condenser that produces an exit vapor temperature of -15EC.

The total number of moles entering the condenser is equal to the sum of the liquid and vapor moles leaving the condenser. This calculation is similar to Step A's (N_2 inerting purge @ 5 scfh) potential controlled calculation method.

The resulting V_A of the iterative calculation is: 0.0337

The mass of each component is related to its moles by:

$$M_i(lbs) = (V_i)(MW_i)$$

 $M_A(lbs) = (0.0337)(58.08)$
= 1.96 lb

A summary of the potential VOC emissions for each of these tanks follows:

1,000 Gallon Tank

		VOC Emissions Per Step, pounds		
Possible Operation Steps	Temp (C)	PU*	PC*	
A. N2 Inerting Purge @5 scfh	20	5.73	0.73	
B. Charge 1000 gal tank 2/3 ful of Acetone	20	3.20	0.41	
C. Heat from 20 C to 55 C	20-55	9.94	0.19	
Atmospheric Distillation D. Heat from 20 C to 56.3 C 5 scfh N2 purge during distillation	20-56.3 56.3	23.19 0.86	0.20 0.09	
Vacuum Distillation E. Evacuation F. Sweep (0.5 scfm leak rate) G. Depressurization from 2 to 1 atmospheres	20 20	13.07 8.21	0.98 2.62	
G. Depressurization from 2 to 1 atmospheres	20	4.02	0.80	

^{*} PU = Potential Uncontrolled, PC = Potential Controlled (8-5-3)

		VOC Emissions Per Step, pounds			
		Per Step, pounds		Yearly,	pounds
Possible Process Chain for 1 Day	Step(s)	PU	PC	PU	PC
Charge - Vac. Dist Depressurize	B-E-F-G	28.50	4.80	10401.98	1753.70
2. Charge - Atm. Dist Depressurize	B-D-G	31.26	1.50	11410.91	548.62
3. Charge - Heat - Depressurize	B-C-G	17.16	1.40	6263.37	511.45
4. Charge - Heat - Depressurize	B-C-G	17.16	1.40	6263.37	511.45
5. Charge - Nothing - Depressurize	B-G	7.22	1.21	2633.51	441.00
6. 24 hour sweep	А	5.73	0.73	2092.69	266.5
Total (pounds)		107.03	11.04	39065.83	4032.72
Total (tons)		0.05	0.01	19.53	2.02

500 Gallon Tank

		VOC Emission poun	• •
Possible Operation Steps	Temp (C)	PU	PC
A. N2 Inerting Purge @5 scfh	20	5.73	0.73
B. Charge 500 gal tank 2/3 full of Acetone	20	1.60	0.20

		VOC Emissions Per Step, pounds			
		Per Step, pounds		Yearly, pounds	
Possible Process Chain for 1 Day	Step(s)	PU	PC	PU	PC
5. Charge (10 times/day)	В	16.00	2.00	5840.00	730.00
6. 24 hour sweep	А	5.73	0.73	2092.69	266.50
Total (pounds)		21.73	2.73	7932.69	996.50
Total (tons)		0.01	0.00	3.97	0.50

SO₂, NOx, CO, and inorganic HAP calculations

SO₂, Nox, and CO emissions may also be emitted from the process vessel Gen'l Tank TK 40-11. There may be processes run where one or more of these pollutants is emitted from a gas evolving process step. Based on Lilly's current knowledge of the processes run at Tippecanoe Laboratories, three different reactions were chosen to obtain an estimate of the potential SO2, NOx, and CO emissions. Each reaction is the highest known emitter of the respective pollutant it emits. There are fewer processes that emit SO₂, NOx, and CO than VOCs. Therefore, 100 lots/yr were used in the worst-case potential emission calculation. This maximum emission rate is much higher than any one tank will emit by itself, but it is difficult to estimate how much of the emissions can be attributed to each individual tank. Therefore, the air emission inventory indicates that the entire building emission comes from each tank by itself. When summing the total emissions, this factor is taken into account by looking at the maximum emitting tank for Building T27.

Inorganic HAPs may be emitted from both tanks.

NOx

100 lots/yr for processes emitting NOx in T27.

Assumed all emissions can come from one tank or several tanks, but no more than a total of 100 lots/yr of any process that emits NOx will run in T27.

Since process stoichiometry is based on bulk facility building scale, scaled emissions from all process to appropriate size of new tanks.

Reaction 1: NaNO2 + HCI -> HNO2 + NaCl 92.3 kg of NaNO2 will be reacted with HCI, therefore: 92.3 kg NaNO2 (1000 g/1 kg)(1 mol/69 g NaNO2) = 1338 mol NaNO2

1338 mol Na NO2 yields 1338 mol HNO2

Reaction 2:

Only half of the 1338 mol HNO2 available reacts.

Therefore, 669 mol of N2O are formed, 669 mol of HNO2 remain.

Nitrous oxide (N2O) is stable and inert.

Total NO2 Formed:

$$669 \ \frac{\text{mol NO2}}{\text{lot}} \ \text{x} \ \frac{46.01 \ \text{g}}{\text{mol NO2}} \ \text{x} \ \frac{1 \ \text{lb}}{454 \ \text{g}} \ \text{x} \ \frac{100 \ \text{lots}}{\text{year}} \qquad 6780 \ \frac{\text{lb NOx}}{\text{lot}} \ \text{(for a 2,000 gallon tank)}$$

Potential to Emit

T27 Gen'l Tank TK 40-11 (1,000 gallons)

SO₂

100 lots/yr for processes emitting SO₂ in T27.

Assumed all emissions can come from one tank or several tanks, but no more than a total of 100 lots/yr of any process that emits SO₂ will run in T27.

Since processes stoichiometry is based on bulk facility building scale, scaled emissions from all processes to appropriate size of the new tanks.

$$1023 \frac{\text{kg SOCl}_2}{\text{lot}} \times \frac{\text{kgmol SOCl}_2}{118.97 \text{kg}} \times \frac{\text{kgmol SO}_2}{\text{kgmol SOCl}_2} \times \frac{64.06 \text{ kg SO}_2}{\text{kgmol SO}_2} \times 2.2 \frac{\text{lb}}{\text{kg}}$$

$$1212 \frac{\text{lb SO}_2}{\text{lot}} \text{ (for a 2,000 gallon tank)}$$

Potential to Emit

T27Gen'l Tank TK 40-11 (1,000 gallons)

$$\frac{1,212 \text{ lb SO}_2}{\text{lot}} \times \frac{100 \text{ lots}}{\text{year}} \times \frac{1,000 \text{ gallon}}{2,000 \text{ gallon}} \times \frac{1 \text{ ton}}{2,000 \text{ lbs}} \qquad \textbf{30.30} \quad \frac{\text{tons SO}_2}{\text{year}}$$

CO

Based on test data from process with worst case CO emissions. The test data was performed on a 1:20,000 scale for a process run in a 2000 gallon scale building.

Process uses 63.5 grams of COCI₂
Assume all is converted to CO (this is a very conservative assumption)

$$63.5 \ \frac{\text{g COCl}_2}{\text{lot}} \ \text{x} \ \frac{\text{gmol COCl}_2}{98.92 \ \text{g}} \ \text{x} \ \frac{\text{gmol CO}}{\text{gmol COCl}_2} \ \text{x} \ \frac{28 \ \text{g CO}}{\text{gmol CO}} \ \text{x} \ \frac{1 \ \text{lb}}{454 \ \text{g}}$$

Potential to Emit

T27Gen'l Tank TK 40-11 (1,000 gallons)

$$\frac{\text{0.0396 lb CO}}{\text{lot}} \times \frac{\text{20,000 bldg size}}{\text{1 sample size}} \times \frac{\text{100 lots}}{\text{year}}$$

$$x \frac{1,000 \text{ gallon}}{2,000 \text{ gallon}} x \frac{1 \text{ ton}}{2,000 \text{ lbs}} \frac{\textbf{19.80}}{\textbf{year}}$$

Inorganic HAP

Based on emission calculations for worst case inorganic HAP emitting process (emits 1829 lb HCl per lot from a 4,000 gallon tank).

Maximum production capacity is based on producing 50,000 kilos of final per year.

Potential to Emit

T27 Gen'l Tank TK 40-11 (1,000 gallons)

NOTE: Emissions do not exactly match those in the table due to rounding in previous calculations

T27 Gen'l Tank TK 53-10 (500 gallons)

Appendix A: Emissions Calculations

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Equipment Leak Fugitives

Company Name: Address City IN Zip: Eli Lilly and Company 1650 Lilly Road, Lafayette, Indiana 47909

CP: 157-12478 PIt ID: 157-00006 ERG/MP Reviewer:

18-Sep-2000 Date:

TK40-11 Tank Replacement Fugitive Emission Calculation

Fugitive Emission Componenet	Number of Components	Uncontrolled En	nissions	Controlled Em		Annual Uncontrolled Emissions (tpy)	Annual Controlled Emissions (tpy)
			,		Daily Emission (lb/day)		
Tank Flanges	23	0.00183	1.0102	0.000697	0.3847		
Pumps & Agitators	1	0.108908	2.6138	0.004969	0.1193		
Liquid Valves	0	0.015653	0.0000	0.001459	0.0000		
Vapor Valves	0	0.012346	0.0000	0.000309	0.0000		
Press Relief Valves	0	0.22928100000000001	0.0000	0.229281	0.0000		
Total VOC Fugitive			3 6340		0.5040	0.6614	0.0020
Emissions			3.6240		0.5040	0.6614	0.0920

TK53-10 Tank Replacement Fugitive Emission Calculation

Fugitive Emission Componenet	Number of Components	Uncontrolled En	nissions	Controlled Em			Annual Controlled Emissions (tpy)
			Daily Emission (lb/day)		Daily Emission (lb/day)		
Tank Flanges	75	0.00183	. ,,	' '	1.2546		
- U	75						
Pumps & Agitators	0	0.108908	0.0000	0.004969	0.0000		
Liquid Valves	1	0.015653	0.3757	0.001459	0.0350		
Vapor Valves	0	0.012346	0.0000	0.000309	0.0000		
Press Relief Valves	0	0.22928100000000001	0.0000	0.229281	0.0000		
Total VOC Fugitive							
Emissions			3.6697		1.2896	0.6697	0.2354